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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,640	02/25/2002	Norikazu Iwase	219581USOPCT	1924

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,640	IWASE ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments the Claims, Remarks, and Information Disclosure Statement received on January 21, 2004. Claims 1 and 3-20 are pending in this application. Claim 2 stands cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama et al (5,236,950).

Aoyama et al discloses a process for hair growth. Example 9 discloses a composition containing 0.1% lavender oil and 0.01% ceramide.

*Lavender oil inherently contains instant terpenes: limonene, α- pinene, and β-pinene in the instant amount. US patent 6,190,685 is cited as art of interest to demonstrate inherency that essential oils contain instant terpenes.

Claims 1, 5, 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nurnberg et al (5,766,628).

Nurnberg et al disclose bath and shower compositions. Example 4 contains 2% ceramide and 5% pine oil. The composition improves skin quality by increasing circulation after application of the composition. See column 10 and column 11, line 14.

*Pine oil inherently contains terpineol in the instant amount. Note Art of Interest US 5998335 to demonstrate inherency.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-4, 6, 8-11, 15-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,495,171. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 recites a lipid selected from natural ceramide, ceramide, or fatty acid esters of steroids in combination with a terpene compound selected from a-pinene, B-pinene, camphene, limonene, B-caryophyllene, a-terpineol, borneol, nopol, isobornylcyclohexanol, santalol, cedrol, guaiol, vetiverol and patchouli alcohol. Claim 2 recites ceramide analog formulas. Independent claim 6 recites a lipid contained in the stratum corneum and cedrol.

US patent claim 1 recites a combination of two ingredients, component A selected from cedrol, patchouli alcohol, and vetiverol and component B selected from four ceramide analog formulas. Claim 7 limits component A to cedrol.

Therefore, US patent recites the species of both the lipid and the terpene compound and is fully encompassed by the instant application, thus it is said to anticipate the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Candau et al (5,776,480) in view of Grieveson et al (5,912,002).

Candau et al disclose a ceramide cosmetic/dermatological composition for dry skin. See column 3 for the compound formula. The composition may contain a combination of ceramide III, V, and II and utilized up to 65%. See column 19-25. The

composition contains lipophilic adjuvants such as essential oils, fatty acids, fatty alcohols, waxes, etc. in the amount of 0.1-20%. See column 4, lines 55-65.

Candau et al do not specify the essential oil.

Grieveson et al disclose a cosmetic composition contains a benefit agent. The benefit agent is an agent that moisturizes, conditions, and protects the skin. See column 2, lines 54-60. Essential oils such as white cedar, orange, eucalyptus, lavender, limonene, and other terpenoid oil are taught as one type of benefit agent. Other benefit agents taught to moisturize the skin are cholesterol and ceramides. The reference teaches a mixture of the benefit agents. See column 3.

*Note that white cedar inherently contains cederol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Candau et al and Grieveson et al and utilize instant essential oils. One would be motivated to do so since Grieveson discloses that these essential oils are utilized to protect and condition the skin. Further, one would expect similar results since Candau et al teach the use of essential oils in a moisturizing composition. Therefore, a skilled artisan would be motivated to add essential oils in the composition to increase the ability of the composition to moisturize and condition the skin and yield an additive effect. It is obvious to combine two components each of which is taught by the prior art to for the same purpose of conditioning and moisturizing the skin, in order to form a third composition for the same purpose of moisturizing and conditioning the skin.

Response to Arguments

Applicant argues that Candau et al fails to disclose or suggest the combination of instant lipids and instant terpene components. It is further argued that Candau et al only disclose a general teaching of the incorporation of essential oils. Applicant argues that Grieveson et al teach a long list of benefit agents and although the agents may be mixed, there is no motivation to combine the agents and recited in claim 1. Lastly, applicant argues unexpected results in the specification Tables 1 and 2.

Applicant's arguments have been fully considered but they are not persuasive. The examiner notes the unexpected results, however it is also noted that the applicant utilizes a specific ceramide analog in a specific weight percent. Applicant has not provided unexpected results comparing the other lipids recited in the claims, i.e. fatty acid esters of steroids. A single specific species does not provide for a generic concept, i.e. the unexpectedness of the specific ceramide analog does not apply to all lipids. Thus, the unexpected results are not commensurate in scope of the claims.

Claims 1 and 3-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/14401 by itself or in view of Hattori et al (6,194,468).

WO teaches a cosmetic composition for improving skin roughness and wrinkles. See page 1. The composition contains instant ceramide derivatives in the amount of 0.001-50% and 0.0001-20% vegetable extracts such as sage, eucalyptus, lemon, and orange peel, among other components (these extracts inherently contain terpene compounds). The extracts are obtained by grinding the whole plant or parts such as leaves, barks, roots, seeds, fruits, and nuts. See page 22. Cholesterol and its derivatives are the preferred sterols taught on page 27 and incorporated in the amount

of 0.01-50%. The composition may contain oily substances such as ester oils (peppermint and eucalyptus oil) in the amount of 0.005-30%, which also contain terpene compounds. See page 43. Terpene alcohols such as farnesol are taught for formulations that condition the hair. See page 53.

WO does not exemplify the instant vegetable extracts or specify all the instant terpenes.

Hattori et al teach farnesol, santalol, and vetiverol are sesquiterpene alcohols and essential oils such peppermint oil, cedar oil, etc. contain terpene compounds. See column 2-3.

*Note that cedar oil inherently contains cedrol.

It would have been obvious to one of ordinary skill in the art at the time the invention was look to WO 97/14401 and utilize the extract of choice. One would be motivated to do so since Hattori teaches the suitability of all the extracts listed on page 27. Note that the vegetable extracts taught such as orange peel, lemon, etc. inherently contain terpenes since WO teaches using the entire plant to obtain the extract. Further, one would be motivated to use a terpene alcohol to formulate a conditioning hair composition since WO specifically teaches a natural terpene alcohol such as farnesol is suitable for hair compositions. Therefore, it is deemed obvious to look at the guidance of WO and arrive at instant composition. Further, if one desired a hair conditioning composition, one would be motivated to add farnesol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO and Hattori et al and utilize the

instant terpene. One would be motivated to do so since Hattori teaches that farnesol, santalol, and vetiverol are sesquiterpene alcohols. Furthermore, Hattori teaches that essential oils such as peppermint oil contain terpenes. Therefore, a skilled artisan could expect similar results by substituting WO's farnesol with the instant terpenes and expect similar results since Hattori et al teaches their functional equivalency. Absent the criticality of the instant terpenes versus WO's farnesol, it is the examiner's position that since the criticality lies in the terpene compound and not the source of the terpene, one would reasonably expect similar results.

Response to Arguments

Applicant argues that WO 97/144401 and Hattori et al fail to disclose or suggest the instant combination has specified in claim 1. It is further argued that the references do not exemplify the claimed composition.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it should be noted that the claims are rejected under obviousness; thus the prior art does not have to exemplify the instant combination, it merely needs to suggest it. It is the examiner's position that WO *by itself* suggests the instant invention. WO teaches the instant lipids (ceramides and esters of steroids) and the terpene compounds. In regards to the terpene compounds, page 21 of the prior art should be noted wherein majority of the plant extracts taught inherently contain terpenes. Further, page 53 clearly directs one to the use of a farnesol, a terpene alcohol, for use in hair compositions. Thus, the motivation to combine the ceramide and terpene compound being that WO directly teaches the combination if one desired a hair care compositions. The deficiency

in WO is the teaching of the instant terpene compounds. It is the examiner's position that the criticality lies in the utilization of a terpene compound and not the type of terpene compound. Thus, a skilled artisan could substitute the farnesol with the instant terpene compound and reasonably expect similar results. To substantiate this argument, the examiner relies on Hattori et al. Hattori et al state that WO's farnesol and the instant terpenes are sesquiterpene alcohols and thus are functionally equivalent. Therefore, a skilled artisan would be motivated to substitute farnesol with the instant terpenes expecting similar results since the said terpenes are functional equivalents.

Although, applicant has not argued unexpected results in reference to the instant rejection, the examiner points out the following. Firstly, as pointed out above the results utilize a specific ceramide analog in a specific amount. Thus, the claims are not commensurate in scope since applicant has not shown that other lipids also provide the said unexpected results. Secondly, the examiner points out that applicant has not provided unexpected results comparing the closest prior art. In instant case, the examiner is stating that farnesol is functionally equivalent to the instant terpene compounds. Thus, unexpected results that would overcome this rejection would compare WO's farnesol and instantly claimed terpenes and demonstrate the criticality of the instant terpenes. In consideration of the above factors, the claims including new claims remain rejected under obviousness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-

242-0614. The examiner can normally be reached on M-F (8:00-5:00) with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

April 21, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER